

REMARKS

By this Amendment, Claims 8-17 are cancelled without prejudice. Applicants reserve their right to include the cancelled claims in a related application, such as a divisional, continuation, or continuation-in-part application.

Subsequent to this amendment, the pending claims are 31-38.

Rejection of Claims 8-17 under 35 U.S.C. 103(a) as being unpatentable over Shor et al in combination with Koskiniemi et al (Page 2 of the Office Action)

These claims have been cancelled.

Rejection of Claims 31-38 under 35 U.S.C. 112, first paragraph

The claims are rejected for the reasons set forth in the Office Action of October 23, 2001. In that Office Action (apparently dated October 24, 2001) the claims are declared to be enabling for the treatment of Alzheimer's disease in a living being having *Chlamydia pneumoniae* infection, but not to be reasonably enabled for the treatment of Alzheimer's disease in a living being not infected with *Chlamydia pneumoniae*. This rejection is respectfully traversed on the grounds that follow.

It is common, when applying a therapeutic method, to know in advance that the treatment may not help all patients treated. Applicants respectfully submit that it is not the policy of the Patent Office, or existing patent law, that a therapeutic method help all patients in order to be patentable.

An independent grounds of traversal is that, for any type of claimed invention, it is not a requirement that all “embodiments” of a claimed invention be functional. Applicants have provided evidence that about 90 per cent of patients with Alzheimer's disease were infected by *Chlamydia* in their brains (either the cerebellum, hippocampus, or parietal cortex; See application page 39 - 42, especially page 39, lines 14-21.)

Consistent with either of the two independent grounds of traversal, it is likely that the claimed therapeutic method would in fact be applied to a patient without knowing for certain whether that patient is infected with *Chlamydia*. That is because determination of whether a person's brain is infected would require an invasive diagnostic technique and such techniques are normally associated with significant risks to a patient.

Post-filing publications related to the issue of the frequency of *Chlamydia* infection in Alzheimer's disease

The attached Information Disclosure Statement (IDS) lists several pertinent articles or abstracts all of which are attached.

The Gieffers et al article asserts that *Chlamydia pneumoniae* is “not a common phenomenon” and the Nochlin et al abstract states “we have not been able to confirm an association of *C. pneumoniae* with AD”, AD referring to Alzheimer's disease.

The Mahony et al abstract (World Alzheimer Congress, 2000), reports that they have demonstrated the presence of *Chlamydia pneumoniae* DNA in 85% of AD cases. Mahony et al. address the discrepancy between the results of those who found *Chlamydia pneumoniae* frequently associated with AD and those who did not. They

state that "Perhaps the discrepancy is due to the low sensitivity of the test and the need to due [sic] replica testing". The second Mahony et al abstract (Chlamydia Research Meeting) made a similar disclosure.

The Ossewaarde abstract reported "The presence of *C. pneumoniae*-specific antigens appears to be strongly associated with Alzheimer's disease and not with other types of dementia." They also conclude that "*C.pneumoniae* antigens are present in the brains of patients with Alzheimer's disease, but not in control patients, ..."

A news article by Habeck discusses various published results regarding the successful attempts to find *C. pneumoniae* in AD, also "a few negative reports", and a prediction by Karl Herrup that *C. pneumoniae* will not turn out to be the cause of all AD.

Additional IDS disclosure

Also enclosed is an article Balin, B.J. et al. 1998, which contains data included in the present application.

In view of the foregoing, allowance of all claims is requested.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
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CERTIFICATE OF MAILING

I hereby certify that the foregoing AMENDMENT and a Petition for an Extension of Time, a Request for Continued Examination Transmittal, an Information Disclosure Statement and the references cited therein, a Request for Changes in Attorney Docket Number, and a Fee Transmittal FY 2003, re Application Serial No. 09/227,749 are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 27TH day of May , 2003.



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Reg. No. 31,253